Institutional Review Board
1325 S. Cliff Ave.
Sioux Falls, SD 57117
(605) 322-4706
www.avera.org

Statement of Compliance

The Avera Institutional Review Board (IRB) is duly constituted, has written procedures for operation, initial and continuing review of clinical trials, prepares written minutes of convened meetings, and retains records pertaining to the review and approval process.

The Avera IRB is organized and operates in full compliance with all relevant federal, state and local regulations and policies governing research with human subjects, as applicable. These include but are not limited to: US Department of Health and Human Services (DHHS) regulations 45 CFR Part 46 and the US Food and Drug Administration (FDA) regulations as described in 21 CFR Parts 50 and 56. The Avera IRB also adopted the standards for conducting clinical research studies as defined in the International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice – E6 (R2). It is expected of all investigators conducting clinical research to adhere to these guidelines.

Avera IRB is registered with FDA and OHRP.

- Institution: Avera Health
- IRB Organization (IORG) Number: IORG0000747
- IRB Registration Number: IRB00010096
- FWA Number: FWA00000426

In addition, the Avera IRB operates in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and the Privacy Rule applicable to research, as described in 45 CFR Parts 160 and 164.

The IRB's primary responsibility is to protect the privacy, safety and welfare of the human subject participating in research.

Tammy Hein
IRB Manager, Research Compliance

Lynn Bartholow
Executive Director of Research Compliance